

JUN 05 2002

K020889

Pg 1 of 2

**510(K) SUMMARY**  
**Endoscopic Light Source XL202/L3**

**I. Submitter:**

WORLD OF MEDICINE Lemke GmbH  
Danziger Strasse 21  
82194 Gröbenzell  
Germany

**II. Device Names:**

- |    |                       |                                  |
|----|-----------------------|----------------------------------|
| 1. | Classification Name:  | Accessory to an Endoscope        |
| 2. | Common or Usual Name: | Endoscopic Light Source          |
| 3. | Proprietary Name:     | Endoscopic Light Source XL202/L3 |

**III. Classification:**

Class II. This device is described in 21 C.F.R. § 876.1500. The product code for the device is GCT.

**IV. Predicate Devices:**

- **Karl Storz Xenon Light Source Model 201320-20 (K934559)** manufactured by Karl Storz Imaging, Inc.
- **Xenon Light Source Auto Lip 5123, Model 2123.011 (K983628)** manufactured by Richard Wolf Medical Instruments Corp.
- **Battery Powered Endoscopic Light Source (K960081)** manufactured by Mitsubishi Cable America, Inc.
- **LH-150** manufactured by Pentax Precision Instrument Corp.
- **LH SC Halogen Light Source** manufactured by Olympus America, Inc.

**V. Intended Use:**

The Endoscopic Light Source XL202/L3 is intended to be used with fiber optic endoscopes to provide illumination of body cavities, hollow organs and canals during endoscopic procedures.

The device is classified as Cardiac Floating (CF) which allows the use in endoscopic cardiac procedures when used in conjunction with the proper instrumentation.

**VI. Device Description:**

The Endoscopic Light Source XL202/L3 uses a 180 W xenon lamp to provide illumination during endoscopic surgery through a fiber optic cable, which is

## **510(K) SUMMARY**

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connected to the device. Furthermore, the light source can be equipped with an additional 150 W halogen lamp for diagnostic applications in endoscopy. The 150 W halogen lamp also function as a backup up lamp to avoid interrupting a procedure in case of a malfunction of the xenon lamp. The color temperature of the xenon lamp and halogen lamp is approximately 6000 °K and 3400 °K respectively, the lamp life approximately 500 hours and 50 h respectively.

### **VII. Substantial Equivalence:**

The Endoscopic Light Source XL202/L3 described in this notification is similar in design and technological characteristics to the **Karl Storz Xenon Light Source Model 201320-20** (K934559) manufactured by Karl Storz Imaging, Inc. and the **Xenon Light Source Auto Lip 5123, Model 2123.011** (K983628) manufactured by Richard Wolf Medical Instruments Corp., the **Battery Powered Endoscopic Light Source** (K960081) manufactured by Mitsubishi Cable America, Inc., the **LH -150** manufactured by Pentax Precision Instrument Corp. and the **CLH-SC Halogen Light Source** manufactured by Olympus America, Inc.

Both the Endoscopic Light Source XL202/L3 and the predicate devices are intended to provide illumination of body cavities, hollow organs and canals during endoscopic procedures.

The differences between the Endoscopic Light Source XL202/L3 and predicate device are minor and raise no new questions of safety and effectiveness.

Accordingly, WORLD OF MEDICINE Lemke GmbH believes that the Endoscopic Light Source XL202/L3 is substantially equivalent to the predicate devices currently on the market.

### **VIII. Performance Data:**

The Endoscopic Light Source XL202/L3 complies with the International Standard IEC 601-1, IEC 601-1-2 and conforms to the Medical Device Directive 93/42/EEC. In addition, the Endoscopic Light Source XL202/L3 meets the requirements of the Underwriters Laboratories standard UL2601-1.

Signed:

S. Raab  
Susanne Raab  
Official Correspondent



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 05 2002

WORLD OF MEDICINE Lemke GmbH  
% Ms. Susanne Raab  
91 Trowbridge Street  
CAMBRIDGE MA 02138

Re: K020889  
Trade/Device Name: Endoscopic Light  
Source XL202/L3  
Regulation Number: 21 CFR §876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: 78 GCT  
Dated: March 15, 2002  
Received: March 19, 2002

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**STATEMENT OF INDICATIONS FOR USE**

APPLICANT: WORLD OF MEDICINE Lemke GmbH

510(K) NUMBER (if known): K 820 889

DEVICE NAME: Endoscopic Light Source XL202/L3

**INDICATIONS FOR USE:**

The Endoscopic Light Source XL202/L3 is intended to be used with fiber optic endoscopes to provide illumination of body cavities, hollow organs and canals during endoscopic procedures.

The device is classified as Cardiac Floating (CF) which allows the use in endoscopic cardiac procedures when used in conjunction with the proper instrumentation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Prescription Use ✓  
(Per 21 CFR 801.109)

Nancy E. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K020889